General

Guideline Title

The prevention of early-onset neonatal group B streptococcal disease.

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The prevention of early-onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2012 Jul. 13 p. (Green-top guideline; no. 36). [46 references]

Guideline Status

This is the current release of the guideline.

This release updates a previously published guideline: Royal College of Obstetricians and Gynaecologists (RCOG). Prevention of early onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Nov. 10 p. (Guideline; no. 36). [39 references]

Recommendations

Major Recommendations

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Classification of evidence levels (1++ to 4) and grades of recommendations (A–D) are defined at the end of the "Major Recommendations" field.

Antenatal Screening

Should All Pregnant Women Be Offered Bacteriological Screening for Group B Streptococcal Disease (GBS)?

D - Routine bacteriological screening of all pregnant women for antenatal GBS carriage is not recommended.

If GBS Is Detected Incidentally Earlier in the Pregnancy, Should Women Be Treated Before the Onset of Labour?

C - Antenatal treatment with benzylpenicillin is not recommended.

Should Women Be Screened for GBS or Receive Intrapartum Antibiotic Prophylaxis (IAP) If GBS Was Detected in a Previous Pregnancy?

D - Current evidence does not support screening for GBS or the administration of IAP to women in whom GBS carriage was detected in a previous pregnancy.

Reducing the Risk of Neonatal GBS Disease in Women Known to Be Colonised with GBS

How Should GBS Bacteriuria in the Current Pregnancy Be Managed?

C - Clinicians should offer IAP to women with GBS bacteriuria identified during the current pregnancy.

Should Women Receive IAP If GBS Is Detected in the Current Pregnancy?

C - IAP should be offered if GBS is detected on a vaginal swab in the current pregnancy.

How Should Women with Known GBS Colonisation Undergoing Planned Caesarean Section Be Managed?

C - Antibiotic prophylaxis specific for GBS is not required for women undergoing planned caesarean section in the absence of labour and with intact membranes.

How Should Women Known to Be Colonised with GBS Who Experience Spontaneous Rupture of Membranes at Term Be Managed?

D - Immediate induction of labour and IAP should be offered to all women with prelabour rupture of membranes at 37^{+0} weeks of gestation or more.

How Should Women with GBS Colonisation and Suspected Chorioamnionitis Be Managed?

A - If chorioamnionitis is suspected, broad-spectrum antibiotic therapy including an agent active against GBS should replace GBS-specific IAP and induction of labour should be considered.

Management of Labour (Including Rupture of Membranes) to Reduce the Risk of Neonatal GBS Disease in Women without Known GBS Colonisation

Should Women Presenting in Preterm Labour with Intact Membranes Be Offered IAP?

C - Women presenting in established preterm labour with intact membranes with no other risk factors for GBS should not routinely be offered IAP unless they are known to be colonised with GBS.

How Should Women with Clinical Risk Factors Such as a Pyrexia (>38°C) in Labour Be Managed?

C - IAP should be offered to women who are pyrexial in labour (>38°C).

How Should Women with Term Prelabour Rupture of Membranes Be Managed?

C - The evidence for IAP for women with term prelabour rupture of membranes is unclear and National Institute for Health and Clinical Excellence (NICE) recommends that it is not given, unless there are other risk factors.

How Should Women with Preterm Prelabour Rupture of Membranes Be Managed to Reduce the Risk of Neonatal GBS Disease?

C - Antibiotic prophylaxis for GBS is unnecessary for women with preterm rupture of membranes.

Should Women with a Previous Baby with Neonatal GBS Disease Be Offered IAP?

D - IAP should be offered to women with a previous baby with neonatal GBS disease.

Which Antibiotics Should Be Given to Prevent Early-onset Neonatal GBS Disease?

B - For women who have accepted IAP, benzylpenicillin should be administered as soon as possible after the onset of labour and given regularly until delivery.

D - Clindamycin should be administered to those women allergic to benzylpenicillin.

Should Vaginal Cleansing Be Performed in Labour?

C - There is no evidence that intrapartum vaginal cleansing will reduce the risk of neonatal GBS disease.

How Should the Newborn Infant Be Managed?

Should Postnatal Antibiotic Prophylaxis Be Given to Low-Risk Term Infants?

C - Postnatal antibiotic prophylaxis is not recommended for asymptomatic term infants without known antenatal risk factors.

How Should the Well Infant with One or More Risk Factors Be Treated?

C - Randomised controlled trials have not provided a sufficient evidence base for clear treatment recommendations in well newborn infants.

How Should the Neonate with Clinical Signs of Early-onset Neonatal Group B Streptococcal (EOGBS) Disease Be Managed?

C - Infants with clinical signs of EOGBS should be treated promptly with appropriate antibiotics.

How Should the Infant of a Mother with a Previous Infant with GBS Disease Be Managed?

C - For a well infant whose mother has had a previous infant with GBS disease, either clinical evaluation after birth and observation for around 24 hours are necessary, or blood cultures need to be obtained and the infant treated with benzylpenicillin until the culture results are available. It is unclear whether further action is necessary for the well infant.

Definitions:

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Grades of Recommendations

A – At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

B – A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C – A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D – Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good practice point – Recommended best practice based on the clinical experience of the guideline development group

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Early-onset neonatal group B streptococcal disease

Guideline Category

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Infectious Diseases

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide guidance for obstetricians, midwives and neonatologists on the prevention of early-onset neonatal group B streptococcal (EOGBS) disease

Note: Prevention of late-onset group B streptococcal disease (GBS) and treatment of established GBS disease is not considered beyond initial antibiotic therapy

Target Population

Pregnant women and newborn infants

Interventions and Practices Considered

Management of Pregnant Women With Early-onset Neonatal Group B Streptococcal (EOGBS) Disease

1. Intrapartum antibiotic prophylaxis (IAP) (to women with a previous baby with neonatal group B streptococcal [GBS] disease or with GBS bacteriuria or in whom GBS is detected incidentally or who are pyrexial during labour)
    - Benzylpenicillin
    - Clindamycin
    - Vancomycin
2. Broad-spectrum antibiotic therapy for chorioamnionitis
3. Vaginal swabs
4. Induction of labour

Management of Infants with Clinical Signs of GBS Disease

1. Clinical evaluation and observation for 24 hours after birth
2. Antibiotic therapy
    - Benzylpenicillin
3. Blood cultures
4. Cerebrospinal fluid culture
5. Lumbar puncture
6. Sepsis evaluation

Note: The following interventions were considered but not recommended: routine bacteriological screening for antenatal GBS carriage, antenatal treatment with benzylpenicillin, screening for GBS or intrapartum antibiotic prophylaxis for women in whom GBS carriage was detected in a previous pregnancy, antibiotic prophylaxis specific for GBS for women undergoing planned caesarean section in the absence of labour and with intact membranes, antibiotic prophylaxis for women presenting in established preterm labour with intact membranes with no other risk factors for GBS, antibiotic prophylaxis for GBS for women with preterm rupture of membranes, ampicillin use, intrapartum vaginal cleansing, postnatal antibiotic prophylaxis for asymptomatic term infants without known antenatal risk factors, and routine surface cultures or blood cultures on well infants.

Major Outcomes Considered

- Incidence of early-onset group B streptococcal (EOGBS) disease
- Side effects of intrapartum antibiotic prophylaxis
- Mortality in EOGBS disease

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The guideline was developed in accordance with standard methodology for producing Royal College of Obstetricians and Gynaecologists Green-top Guidelines. The Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), EMBASE, Medline and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. The search was restricted to articles published between 2003 and August 2011. Search terms included: 'group B streptococcus', '*Streptococcus agalactiae*', 'group B streptococcus and pregnancy', 'beta haemolytic streptococcus and pregnancy', and 'beta haemolytic streptococcus and neonatal', 'beta hemolytic streptococcus and neonatal', 'GBS bacteriuria', and was limited to humans and the English language. The National Library for Health and the National Guideline Clearinghouse were also searched for relevant guidelines and reviews. Studies relevant to the scope of the guideline were selected by the members of the guideline development group. Where possible, recommendations were based on available evidence. Areas lacking evidence were highlighted and annotated as 'good practice points.'

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Reviewing and Grading of Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html). An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2–) will be excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality

RCTs when higher-quality observational evidence is available.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A – At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

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Extrapolated evidence from studies rated as 1++ or 1+

C – A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D – Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good practice point – Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate screening and management for the prevention of early-onset neonatal group B streptococcal disease

Potential Harms

Antenatal screening and treatment may carry disadvantages for the mother and baby. These include anaphylaxis, increased medicalisation of labour and the neonatal period, and possible infection with antibiotic-resistant organisms, particularly when broad-spectrum antibiotics such as amoxicillin are used for prophylaxis.

Qualifying Statements

Qualifying Statements

- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research might be indicated.
- The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available within the appropriate health services. This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive

protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The prevention of early-onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2012 Jul. 13 p. (Green-top guideline; no. 36). [46 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 Nov (revised 2012 Jul)

Guideline Developer(s)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

Guideline Committee

Guidelines Committee

Composition of Group That Authored the Guideline

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Peer Reviewers: British Association of Perinatal Medicine; British Maternal and Fetal Medicine Society; British Infection Association; Consumers' Forum; Group B Strep Support; Women's Services Pharmacists Group, Leeds; National Childbirth Trust; Royal College of Paediatrics and Child Health; UK National Screening Committee; Department of Health; Mr FA Boret FRCOG, London; Dr N El Helali, Paris Saint-Joseph; Mr M J Heard FRCOG, Winchester; Dr R Imtiaz MRCOG, Worcestershire; Dr G Kumar FRCOG, Chester; Dr PT Lynch MRCOG, Dundee; Ms L Muir, Ayrshire Maternity Unit, Crosshouse Hospital, Kilmarnock; Dr J Sandoe, Leeds Teaching Hospitals NHS Trust, Leeds General Infirmary; Dr A Simm MRCOG, Nottingham; Professor PJ Steer FRCOG, London

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Financial Disclosures/Conflicts of Interest

Conflicts of interest: None declared.

Guideline Status

This is the current release of the guideline.

This release updates a previously published guideline: Royal College of Obstetricians and Gynaecologists (RCOG). Prevention of early onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Nov. 10 p. (Guideline; no. 36). [39 references]

Guideline Availability

Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .

Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .
- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the RCOG Web site .

- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the RCOG Web site .
- RCOG Audit on the prevention of neonatal Group B Streptococcal disease. 2007 Jan. 78 p. Electronic copies: Available from the RCOG Web site .

Appendix I of the original guideline document contains a chart listing estimates of the risk of early-onset group B streptococcal (EOGBS) disease in the presence of individual antenatal risk factors, with and without intrapartum antibiotic prophylaxis (IAP). Appendix II lists indications for offering GBS-specific IAP.

Suggested audit topics are provided in section 10 of the original guideline document.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on October 14, 2005. This NGC summary was updated by ECRI Institute on August 23, 2012. The updated information was verified by the guideline developer on September 25, 2012.

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